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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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**GRAYBEAL JACKSON HALEY LLP**

Frederick A. Kaseburg

Suite 350

155 - 108th Avenue NE

Bellevue, WA 98004-5901

EXAMINER

REICHLE, KARIN M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/668,939

Applicant(s)

NICHOLSON, MICHEAL E.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2006 and 21 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 8-23-05 did not include a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but needs a fee charged before consideration. Once such fee has been charged the information referred to therein will be considered. It should be noted however that the reference cited therein has already been made of record on the PTO-892 which accompanied the 4-18-05 Office Action.

### ***Specification***

#### ***Drawings***

2. The drawings are objected to because Figure 1 should be labeled "PRIOR ART". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Description*

3. The disclosure is objected to because of the following informalities: 1) The description of Figure 1 in paragraph 10 is still incomplete, i.e. it is prior art also, see paragraph 15. 2) In paragraph 1, "priority from" still needs to be changed to --the benefit of--.

3) Applicant now claims the second sheet of material defining an expandable opening without including "auxiliary" structure yet describes the second sheet as including stretchable stitching and being a "base" material. Applicant has not explicitly defined either the terminology "auxiliary" or "base" in the specification and therefore such will be given its broadest usual definition, i.e. its dictionary definition. The dictionary defines "auxiliary" as "offering or providing help, functions in a subsidiary capacity" and "subsidiary" is defined as "forming aid or support; auxiliary" and "base" is defined as "a supporting part or layer; foundation". Since "auxiliary" and "base" are so defined by the dictionary and paragraphs 17 and 22-24 and the Figures describe the opening as having a seam or serging or there being elasticity in the material 48 and claims 7 and 12 describe the opening having stretchable stitching and the second sheet being of "base" material it appears that at the very least the description of the definition of the opening is inconsistent throughout the specification because the opening defined by the "base" material of the second sheet includes auxiliary or subsidiary structure. See also discussion *infra*.

A clear, consistent description, both textual and pictorial, of the second sheet and opening should be set forth throughout the entire application.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: at the very least, a positive antecedent basis for the terminology “stoma to ostomy appliance connector” should be set forth if such is just another term for something that has already been described using other terms.

***Claim Rejections - 35 USC § 112***

5. Claims 1-3 and 5-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With regard to claim 1, lines 5-10, claim 7 and claim 12, see discussion in paragraph 3, section 3 supra. Therefore, at most, where is there original support for a second sheet including a “base” material and defining an opening without inclusion of “auxiliary” structure but including stretchable stitching therearound? With further regard to claim 12, while paragraph 23 provides support for the first and second sheets each comprising the same material and the material of the second sheet also being a “base” material for the sheet because it forms the foundation for the “auxiliary” stretchable stitching 47 of the sheet, where is there original support for the first and second sheets each comprising the same “base” material? With regard to the last four lines added to claim 1, while the application provides original support for the first sheet having at least one low coefficient of friction surface and a second sheet of breathable material, where is the original support for the first and second sheets of material as now set forth

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in these last four lines? Where is the original support for claim 3? Note lines 8-10 of paragraph 23. Finally while paragraph 23 provides original support for a finished diameter of an opening being less than the outside diameter of an adhesive portion, where is the original support for what is claimed in claim 8 which is not the same as that originally described?

6. Claims 1-3 and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For the reasons set forth in paragraph 3, section 3 supra, it is unclear what the structure of the second sheet is, i.e. what is precluded by the terminology “without inclusion of auxiliary structure”? Note again claims 7 and 12. In claim 3, a positive antecedent basis for “the volume” on line 2 should be set forth.

#### ***Claim Language Interpretation***

7. “Auxiliary” and “base” are interpreted as defined supra in paragraph 3., section 3). It is noted that the claims do not claim an ostomy appliance just the cover therefor.

#### ***Claim Rejections - 35 USC § 102***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-3, 5-8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Honig ‘054.

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Claims 1, 10-11: see Figures 1 and 3-4, col. 1, lines 47-49, col. 2, lines 14-16, 44-47 and 65 et seq, col. 3, lines 1-5, col. 4, lines 10-14, 18-19, 21-24, 32-34 and 55-56, col. 5, lines 15-21 and the claims, the Claim Language Interpretation section supra, paragraph 21 of the instant application, i.e. describes a low coefficient of friction surface includes surfaces of a material having a smooth, silky or satiny surface, the dictionary definition of “soft” which is “smooth or fine to the touch”, “easily molded, cut, or worked”, “yielding readily to pressure or weight”, the dictionary definition of “fabric” which is “a cloth produced especially by knitting, weaving or felting fibers”, the dictionary definition of “flexible” which is “capable of being bent or flexed, pliable”, the dictionary definition of “resilient” which is “the property of material that enables it to resume its original shape or position after being bent, stretched or compressed, elasticity”, and paragraph 22 of the instant application, i.e. describes a breathable material includes fabric materials having a weave and perforated materials, i.e. the cover 10 includes first and second sides 42 and 40 of “soft” (i.e. smooth, easily molded, yielding), cotton “fabric”, i.e. woven, which are dimensioned to substantially cover respective first and second portions of an ostomy appliance, the second side 40 including a “resilient”, ribbed aperture “formed” therein which can be expanded to allow the appliance to pass therethrough. It is the Examiner’s first position that the Honig reference teaches first and second sheets of “flexible” material because it teaches a “soft” “fabric”, i.e. moldable, yieldable, that the side 40 is a second sheet which defines an opening therein without the inclusion of auxiliary structure since the “resilient”, ribbed aperture thereof is “formed” therein, that the first side has a coefficient of friction less than the second side because it teaches a “soft”, i.e. smooth, surface and the second side includes a “ribbed”, see definition infra, surface, i.e. aperture, that the second side is elastic and has a greater vapor

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permeability which permeability is greater than that of the first side and allows passing without distortion because it is not only woven fabric but also includes “resilient” opening or aperture 48. In any case, i.e. the Examiner’s second position, the Honig device teaches first and second “soft” “fabric” (i.e. smooth, yielding, woven) sheets dimensioned to substantially cover the appliance and the second sheet includes an expandable, i.e. “resilient”, ribbed opening for passing of the appliance therethrough. Therefore, even if the reference does not explicitly teach the properties of flexibility, friction, elasticity, vapor permeability and no substantial distortion, there is sufficient factual basis for one to conclude that the properties, functions and capabilities are also inherent in the structure of the Honig device since it also teaches the same structure claimed and/or disclosed as providing such properties, functions and capabilities in the instant application, see MPEP 2112.01. Finally, i.e. the Examiner’s third position, even if in either of the two positions discussed supra the structure 48 is “auxiliary” to the side 40, the first sheet as claimed can also be considered 42 and 40 and the second sheet as claimed can also be considered just 48.

Claim 2: See, e.g., claim 5 or Figure 4 of Honig.

Claims 3 and 8: See, e.g., col. 4, lines 29-32, i.e. “close” as defined by the dictionary is “fitting tightly” and “tightly” is defined as “compressed, leaving few or no intervening spaces, compact, snug”, and col. 5, lines 12-17, i.e. “resilient”, see definition set forth supra. It is the Examiner’s first position that the Honig reference teaches a volume as set forth on lines 2-4 of claim 3 and the diameter as claimed in claim 8 because at least the “resilient” aperture 48 defines a volume less than that of the portion of the ostomy appliance it surrounds such that at least such portion of the appliance is subject to a counterexpansion bias when enveloped thereby. It is



noted that the claim does not require the volume of the appliance be that of the entire appliance nor that the entire appliance be subject to the bias. In any case, i.e. the Examiner's second position, the Honig device teaches first and second "soft" "fabric" (i.e. smooth, yielding, woven) sheets dimensioned to substantially cover the appliance and the second sheet includes an expandable, i.e. "resilient", ribbed opening for passing of the appliance therethrough which is in "close tolerance" therewith. Therefore, even if the reference does not explicitly teach the property of counter expansion bias, there is sufficient factual basis for one to conclude that the properties, functions and capabilities are also inherent in the structure of the Honig device since it also teaches the same structure claimed and/or disclosed as providing such properties, functions and capabilities in the instant application, see MPEP 2112.01.

Claims 5-6: See Figures of Honig.

Claim 7. This claim recites the perimeter of the expandable opening includes stretchable stitching. "Stitch" as defined by the dictionary is "a single loop of yarn around an implement such as knitting needle", "the link, loop or knot made in this way". Honig teaches an expandable opening including a ribbed aperture constructed of a resilient member. See the definition of "resilient" supra, i.e. stretchable, and the dictionary defines "ribbed" as "a raised ridged or wale in knitted material or cloth" and "knitted" as "to make or fashion by intertwining yarn or thread in a series of connected loops either on a machine or by hand". Therefore, Honig teaches an expandable opening including stretchable stitching.

Claim 12: See, e.g., col. 5, lines 17-19 and the portions cited supra of Honig.

Claim 13: Claim 13 recites the opening and second sheet being selected to permit the appliance to pass therethrough without substantial distortion. See the discussion in paragraph 12 infra and the discussion of claim 1 supra.

***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honig.

Claim 9 recites the range of coefficients of friction which are considered to provide low friction surfaces, i.e. smooth surfaces. While Honig does not teach such specific range of smoothness it does teach the desirability of using a soft, i.e. smooth, surfaced fabric to form the first and second sheets. Furthermore, where the general conditions of a claim are disclosed in the prior art, i.e. in the present case the smoothness of the fabric, it is not inventive to discover the optimum or workable ranges thereof by routine experimentation, see *In re Aller et al*, 105 USPQ 233.

***Double Patenting***

12. Applicant is advised that should claim 1 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Compare claim 1, lines 5-10 of claim 1 to claim 13.

***Response to Arguments***

13. Applicant's remarks have been considered but are either deemed moot in that the issue has not been reraised or deemed not persuasive because they are narrower than both the original disclosure, e.g. where is "auxiliary" defined in the instant specification as set forth on page 8, first full paragraph of the response, and the teachings of the prior art, see, e.g., prior art rejection supra.

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The other cited prior art also teaches various covers or low coefficient of friction materials.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to claims 1, 3, 8, 12 and 13.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
April 22, 2006